

# EXHIBIT H-1

# Insightsfeature

February 28, 2017

## The Balancing Act

Helping Ensure Appropriate Access  
to Opioids While Minimizing Risk



## A National Crisis

The case against frequent, long-term opioid use continues to gain strength. As recently as mid-February, the **American College of Physicians recommended trying non-medical first-line treatments for lower back pain**, the most common reason Americans visit a doctor. The recommendation was based on a review of literature with the overwhelming evidence indicating that opioids do not effectively treat lower back pain and increase the risk of abuse and addiction. The opioid epidemic was, of course, center stage during the presidential race, with Donald Trump and other candidates vowing to fight prescription drug abuse.

In fact, one of the few Obama-era policies Trump has voiced support for was **legislation signed into law in mid-2016** intended to provide medical professionals and law enforcement officials with more tools to help

people addicted to drugs. It improves treatment for the incarcerated and, importantly, expands access to a drug that can be used by emergency medical workers to reverse overdoses. Currently, naloxone, by standing order, is available in 39 states.

Passage of a package of bills targeting opioid abuse followed the publication of a new prescribing guideline from the Centers for Disease Control and Prevention (CDC) in 2016, to promote medically appropriate use of prescription painkillers. The 12 underlying recommendations are designed to **help primary care providers make informed prescribing decisions** and improve patient care for those with chronic pain “while reducing the number of people who **misuse, abuse or overdose from these drugs.**”

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The guideline emphasizes greater communication and collaboration between prescribers and patients, and focuses on:

- The decision to begin or continue the use of opioid analgesics to treat patients with chronic pain, who are not receiving cancer treatment, palliative care or end-of-life care
- The selection of an opioid analgesic — including dosage, duration of therapy, follow-up and when to discontinue opioids
- Identifying and mitigating opioid analgesic misuse

Shortly after the CDC published its guidance, the U.S. Food and Drug Administration announced **new labeling requirements** warning of the risk of “misuse, abuse, addiction, overdose and death” from opioid analgesics. And in August 2016, for the first time ever, the **U.S. surgeon general, reached out to all physicians** with a plea, asking for their help “to solve an urgent health crisis facing America: the opioid epidemic.”

Painkiller prescriptions have  
**skyrocketed since the 1990s**



**61%** of all drug overdose deaths involved a prescription opioid

Prescription opioids account for approximately **70%** of fatal prescription drug overdoses

In an average month, **4.3M** Americans used painkillers for nonmedical reasons

Prescription drug overdose, abuse and dependence has a societal economic burden of more than **\$78.5B**

## Heading Off Abuse at the Prescription Pad

The actions by the federal government come amidst recognition of the staggering individual and societal implications – and a growing awareness that **corrective action is imperative**. As we discussed before, **painkiller prescriptions have skyrocketed since the 1990s**, increasing fourfold from 1999 to 2014, even as Americans reported no corresponding increase in pain. In 2014, nearly **61 percent of all drug overdose deaths involved a prescription opioid**. Prescription opioids account for approximately **70 percent of fatal prescription drug overdoses**. Prescription drug overdose, abuse and dependence has a societal **economic burden of more than \$78.5 billion**. In an average month, 4.3 million Americans **used painkillers for nonmedical reasons**.

Patient care and pain relief are important components of better health outcomes. Payors need to implement evidence-based programs that support their plan members with the care and pain relief they need – while also identifying at-risk patients and working to head off potential problems. The most effective line of attack in the face of this epidemic is to prevent abuse, addiction and dependency from occurring in the first place.

There are some hopeful signs. A recent IMS Health Inc. study found a notable – and reassuring – **12 percent decline in opioid analgesic prescriptions** since 2012. But focused action is needed to reverse the overall trend of opioid abuse.

As many as **25%** of patients receiving Rx opioids long-term in a primary care setting struggle with addiction



## Management to Help Ensure Appropriate Use

People with chronic pain deserve relief. However, that need is best served when they're prescribed the most effective treatment option — whether opioid analgesics, non-opioid pain medications or physical therapy — and when they understand the associated risks and benefits.

Pharmacy benefit managers (PBMs) play an important role in implementing the CDC guideline, and helping ensure access and patient safety. We have taken a thoughtful, evidence-based approach to implementing the CDC guideline into our utilization management (UM) criteria with consideration of the needs of those with chronic pain, as well as the potential for harm from these powerful medications.

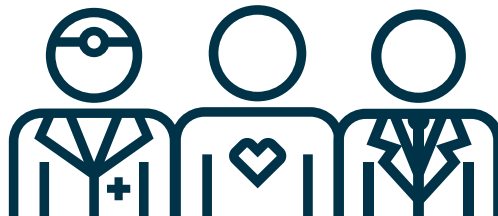
A well-designed UM strategy helps to ensure appropriate utilization, avoid excessive quantities of opioids being prescribed, and covering opioids in situations where

these medications should not be used. When establishing UM protocols such as step therapy guidelines and quantity limits, we consider clinical factors such as diagnosis, concurrent medications, appropriate dosing, and duration of use. For example, patients with cancer, palliative or end-of-life care are screened out of these criteria. Plan sponsors should also carefully consider the needs of their patient population so that they are balancing patient access and safety.

Helping ensure members have the access they need requires ongoing, thoughtful evaluation, given the very real risk of abuse, addiction or dependency with potent opioid analgesics, so that appropriate safeguards are in place. Members prescribed opioid analgesics for chronic pain should be evaluated for risk factors — especially previous instances of misuse — and monitored for signs of abuse.

### At reassessment, clinicians should determine whether:

- Treatment goals are being met, including sustained improvement in pain and function
- The patient has experienced adverse events or shows signs of opioid use disorder, such as difficulty controlling use, or work or family problems related to opioid use
- Benefits of opioids continue to outweigh risks
- Opioid dosage can be reduced or its use can be stopped



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## UM Strategies Based on Clinical Considerations

An article co-authored by the head of the CDC and published in the [The New England Journal of Medicine](#) highlights the three underlying principles of the CDC guidelines:

- 1 For relief of chronic pain not related to end-of-life, palliative or active cancer care, opioids should be prescribed only when pain relief and function improvement are likely to offset the risk of abuse, addiction and dependence
- 2 When opioids are used, they should be used at the lowest dose for the shortest period of time
- 3 Prescribers should use caution when prescribing opioids and continuously monitor patients using them for adverse consequences and to ensure treatment goals are being met



The guideline also emphasizes the need to offer medication-assisted treatment for patients with opioid use disorder

Our UM criteria reinforce these principles and encourage appropriate use of opioids by patients and prescribers. They provide coverage that fosters safe use of opioids, consistent with the new morphine milligram equivalent (MME)-based CDC guideline, to support plans helping members on their path to better health. CVS Health will offer both the new CDC guideline-based, and the older FDA labeling-based programs, as standard. Clients will have the ability to select either option.

## Our UM Approach

We studied our population and the risk for disruption before defining duration of use, dosing and quantity limits. Our UM guidelines based on the new CDC recommendations include:



**MME-based quantity limits.** When prescribing opioids, the CDC advises physicians to “start low and go slow” to ensure patients receive the lowest effective dose and are not unnecessarily prescribed, or moved to, higher doses.

Our CDC-based UM criteria specify more restrictive initial and ceiling limits based on MME. New initial limits for obtaining opioids without prior authorization (PA) will be up to 90 MME per day. Quantities higher than that would require PA and be limited to a maximum of up to 200 MME per day unless minimum FDA-labeled strength, dose or frequency exceeds that limit.



**PA quantity coverage duration.** PA approvals for higher than 90 MME per day will last one month for acute, and 12 months for chronic pain, as long as the prescriber attests to reassessing patient’s pain and medication needs within one month after the initial prescription or dose increase and every three months thereafter. The program identifies and screens out patients with cancer, palliative or end-of-life care.



**Step therapy for extended-release/long-acting opioid analgesics (ER/LA) for chronic pain.** Prescriptions for new starts of ER/LA opioids will only be approved if an immediate-release opioid has been tried first.



**Ten-day supply quantity limit for treatment of acute pain.** Long-term opioid use often begins with treatment of acute pain and the CDC guideline says there is rarely a need for more than seven days of opioids for acute conditions. New starts of immediate-release opioids for acute pain will be limited to a 10-day supply. If treatment is needed beyond 10 days, a higher quantity may be provided when certain coverage conditions are met.



**No initial PA for combination buprenorphine-naloxone products.** Initial PA and quantity limits in place for buprenorphine monoproduct with emergency supply permitted while PA is processed.

## Rates of opioid prescribing can vary three-fold between states



**143 Rxs**

per 100 people  
in Alabama and Tennessee



**52 Rxs**

per 100 people  
in Hawaii

## Additional Resources

- [Guideline for Prescribing Opioids for Chronic Pain; Improving Practice Through Recommendations](#)
- [Increases in Drug and Opioid-Involved Overdose Deaths — United States, 2010–2015](#)
- [CDC Guideline Information for Providers](#)
- [CDC Guideline for Prescribing Opioids for Chronic Pain; Promoting Patient Care and Safety](#)

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**Troy Brennan, MD**

Executive Vice President, Chief Medical Officer



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**[Insights@cvscaremark.com](mailto:Insights@cvscaremark.com)**